UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,034	10/03/2006	Fraser W. Scott	034205.003 (08899427US1)	5076

61690 7590 10/13/2011

SUZANNAH K. SUNDBY
SMITH, GAMBRELL & RUSSEL, LLP
1130 Connecticut Avenue, NW
Suite 1130
WASHINGTON, DC 20036

EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
10/13/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SSUNDBY@SGRLAW.COM
dcdocketing@sgrlaw.com

Office Action Summary	Application No.	Applicant(s)
	10/597,034	SCOTT ET AL.
	Examiner	Art Unit
	G. R. Ewoldt, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2011 and 19 August 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,21,24,25 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,21,24,25 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, remarks, IDS, and 1.132 declarations of Inventors Scott and MacFarlane, filed 5/19/11, are acknowledged.

2. Claims 1, 3-5, 21, 24, 25, and 36 are under examination.

3. In view of Applicant's amendment the previous rejection under the first paragraph of 35 U.S.C. 101 has been withdrawn.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 4 stand rejected under 35 U.S.C. 102(b) as being anticipated by MacFarlane et al. (2003, IDS).

As set forth previously, MacFarlane et al. teaches a Glb1 isoform, the protein expressed from clone WP5212, comprising the EEQLRELRRQ amino acid sequence of SEQ ID NO:1 (see particularly, EXPERIMENTAL PROCEDURES, page 55, wherein the protein is expressed). The reference further teaches the protein attached to a support (see particularly *One and Two-Dimensional Western Blotting*, page 57, wherein the peptide is attached to nitrocellulose).

Applicant's arguments, filed 4/19/11, have been fully considered but are not found persuasive. Applicant cites 1.132 declarations of Inventors Scott and MacFarlane wherein the authors declare that the WP5212 clone was not publically available before 1/09/04.

The cited reference was published in the *Journal of Biological Chemistry* (JBC) on 1/03/03. From the JBC website:

> Ethics
> As a condition of publication, all authors must transfer copyright to the American Society of Biochemistry and Molecular Biology Inc. Manuscripts submitted under multiple authorship are reviewed on the assumption that all listed authors concur in the submission and that the final version has been seen and approved by all authors. Corporate authorship is not accepted.

> Allegations of fraud or misconduct -- be they violations of the standard norms for publishing original research, publication without approval of all authors, plagiarism, republication of data used previously without acknowledgement, or inappropriate graphics manipulation -- will be investigated thoroughly. If, after due process involving the JBC editors, editorial staff and the ASBMB Publications Committee, a paper is found to contain ethical violations, it will be rejected or withdrawn and the matter referred to institutional officials.
>
> Authors of papers published in the JBC are obligated to honor any reasonable request by qualified investigators for unique propagative materials, such as cell lines, hybridomas, DNA clones and organisms that are described in the paper. The primary data obtained from genome- or proteome- scale analyses must be submitted for review in electronic form and, if the manuscript is accepted, must be published as supplemental data in JBC Online. If computer software programs are developed and used in submitted manuscripts, the programs must be made available to the reviewer upon request. The source code or the program must be made available, either commercially or in downloadable form from the authors, if the manuscript is accepted for publication. The Editors may deny further publication rights in the journal to authors unwilling to abide by these principles.

Note particularly the last paragraph.

On submission of an article for publication authors are required to sign statements to the effect that they will observe a journal's policies and ethics. In this instance, the Inventors would seem to be declaring that they would have violated the ethics of the journal in which they published their work, i.e., they seem to be declaring that they would have committed scientific misconduct. A declaration of intent to commit scientific misconduct does not comprise a persuasive argument.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 3 stands rejected under 35 U.S.C. 103(a) as being unpatentable over MacFarlane et al. (2003, IDS) in view of U.S. Patent No. 6,803,221.

As set forth previously, MacFarlane et al. has been discussed above.

The reference teaching differs from the claimed invention in that it does not teach the diabetogenic epitope of Glb1 further comprising a protein or peptide that does not occur in nature.

The '221 patent teaches that proteins or peptides of interest are routinely attached to other proteins or peptides for numerous reasons (see the entire document). Specifically, proteins or peptides are routinely attached to histidine hexamers (which would not be considered to be naturally occurring) to facilitate the purification of the protein or peptide (see particularly, column 14, lines 50-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to fuse the histidine hexamer of the '221 patent to the Glb1 protein of MacFarlane et al. to facilitate the purification of the recombinant protein such that it might be used in the autoantibody assays of MacFarlane et al..

Applicant argues the deficiency of the primary reference.

See the examiner's response in part 5 above.

8. Claims 4 and 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over MacFarlane et al. (2003, IDS) in view of U.S. Patent No. 6,927,041.

As set forth previously, MacFarlane et al. has been discussed above.

The reference teaching differs from the claimed invention in that it does not teach the diabetogenic epitope of Glb1 attached to a support such as a bead, a plate, or a slide.

The '041 patent teaches that proteins or peptides of interest are routinely attached to a bead, a plate, or a slide to facilitate separation and to accommodate assays (see particularly column 22, line 60 - column 23, line 15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to attach the Glb1 protein of MacFarlane et al. to the bead, plate, or slide of the '221 patent to the Glb1 protein of MacFarlane et al. to facilitate separation and to accommodate assays.

Applicant argues the deficiency of the primary reference.

See the examiner's response in part 5 above.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

10. Claims 1, 3-5, and 36 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,214,786.

As set forth previously, The '786 patent teaches the amino acid sequences of SEQ ID NO:1 and SEQ ID NO:4 (SEQ ID NO:118,877 in the '786 patent). The reference further teaches peptides with conservative substitutions, i.e., a substituted protein of SEQ ID NO:118,877 in the '786 patent would comprise a peptide of SEQ ID NO:1 that does not occur normally in nature (see particularly column 9, lines 37-40). The reference further teaches antibody probes specific for the peptides and proteins of the reference (see particularly column 10, line 25) as well as ELISAs (see particularly column 14, line 22) and arrays (see particularly column 16, lines 19-32), both of which would inherently comprise plates and supports.

Applicant's arguments filed 4/19/11 have been fully considered but are not found persuasive. Applicant argues that the reference does not teach SQ ID NO:1.

Applicant's argument that SEQ ID NO:211,164 in the reference is not identical to SEQ ID NO:1 of the instant application is correct. This was a typographical error. Accordingly, that portion of the grounds for rejection has been withdrawn. However, SEQ ID NO:118,877 in the reference is identical to SEQ ID NO:4 of the instant application. Further, SEQ ID NO:118,877 includes SEQ ID NO:1 of the instant application (amino acids 309-318 of SEQ ID NO:118,877). Accordingly, the rejection has been maintained.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 21, 24, and 25 stand rejected under 35 U.S.C. 103(a) each as being unpatentable over U.S. Patent No. 7,214,786 in view of U.S. Patent No. 4,281,061.

As set forth previously, The '786 patent has been discussed above.

The reference differs from the claimed invention only in that it does not teach the claimed reagents in a kit form.

The '061 patent teaches that reagents can be provided in kits as a matter of convenience and for the optimization of their use (see particularly column 22, line 62 - column 23, line 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the reagents of the '786 patent in the kit form of the '061 patent. One of ordinary skill in the art would have been motivated to provide said kit given the teachings of the '061 patent that reagents can be provided in kits as a matter of convenience and for the optimization of their use.

Applicant argues the deficiency of the primary reference.

See the examiner's response in part 10 above.

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from

7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla, can be reached on (571) 272-0841.

16. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

/G.R. Ewoldt/
G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600